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From: Donna Garren [DGarren@uffva.org]  
Sent: Tuesday, December 23, 2003 4:49 PM  
To: fdadockets@oc.fda.gov  
Subject: Submission of Comments for Docket Number: 02N-0278--FDA Interim Final Rule for Prior Notice of Imported Foods

To Whom It May Concern:

I have attached comments on behalf of the members of United Fresh Fruit and Vegetable Association. If you have any questions about the attached document, please feel free to contact me.

Thank you,

Dr. Donna M. Garren

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United Fresh Fruit &  
Vegetable Association

December 23, 2003

Division of Dockets Management  
(HFA-305)  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Re: Docket No. 02N-0278, Interim Final Rule for Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (68 Federal Register 58,974; October 10, 2003); Submission of comments.

Dear Sir or Madam:

The United Fresh Fruit & Vegetable Association (United) is pleased to provide comments on the Interim Final Rule for Prior Notice of Imported Food contained in Docket Number 02N-0278. This rule was developed by the Food and Drug Administration (FDA) to fulfill its obligations set forth by provisions of Title III, Subtitle A, Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act").

United is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States. United members provide the leadership to shape business, trade and public policies that drive our industry. Working with thousands of industry members, United provides a fair and balanced forum to promote business solutions; helps build strong partnerships among all segments of the industry, promotes increased produce consumption; and provides scientific and technical expertise essential to competing effectively in today's marketplace.



## **Introduction**

The dramatic impact of the terrorism attacks of September 11, 2001 has led to a new focus in public policy aimed at promoting greater safety and security and preventing terrorist action. As our members provide over 1,000 different fresh fruits and vegetables to American consumers from both domestic growers and around the world, we take seriously our responsibility for prevention, detection, and all necessary actions to protect consumers from intentional contamination of our products.

We continue to encourage FDA to issue final regulations that allow flexibility and take into account the produce industry's diversity of products and complexity of global production and distribution. Flexibility is critical in that many prescriptive recommendations would be inappropriate or not applicable to our diverse industry.

We applaud the FDA for its leadership in ensuring that appropriate steps are in place to minimize the potential of terrorist action to contaminate foods. United was very pleased with the efforts of FDA to partner with other agencies involved in importation of foods, namely the Bureau of Customs and Border Protection (CBP). Continuing to ensure the safety and security of fresh fruits and vegetables whether produced domestically or abroad is a top priority of the entire produce industry. However, we still have serious reservations pertaining to certain provisions of FDA's Interim Final Rule for Prior Notice of Imported Food.

## **Statutory Authority of Prior Notice Information**

The rule will require that the prior notice include significantly more information than the Bioterrorism Act requires. The required information far exceeds what is necessary to enable FDA to identify articles of food offered for import that need be inspected. United questions whether FDA has the statutory authority to require the prior notice information outlined in the regulation. The proliferation of data required will take much longer and require considerably more resources than currently necessary. This requirement will result in many more prior notice filings without in any way aiding FDA's ability to identify imports of high risk and for scheduling routine inspection.

## **FDA Integration with Existing Import Regulatory Requirements**

It was very encouraging to see FDA's efforts to integrate the agency's requirements with those of CBP. Having options available to the prior notice filer for submission of the required prior notice through either the system used currently for entry of imports – FDA's Operational and Administrative System for Import Support (OASIS) system and Customs' Automated Broker Interface (ABI) of the Automated Commercial System (ACS) (collectively the ABI/ACS-OASIS system) or the FDA web-based Prior Notice (PN) System is a positive step forward. In addition, since importation of foods occurs 7 days a week, 24 hours a day, we were please to see that FDA has announced that the agency will review prior notice submissions transmitted through the ABI/ACS-OASIS and the FDA PN Systems during these hours.

## **Grower Information**

For “foods in their natural state,” the Interim Final Rule requires importers to include grower information “if known.” This requirement is very troublesome. A single shipment of fresh fruit may include identical product from hundreds of growers, all of whom are known by the submitter of the prior notice. Requiring hundreds of prior notices to be submitted for a single shipment seems unnecessarily burdensome. Compliance with this requirement could place a great burden on importers of fresh produce. The reporting of hundreds of growers and growing locations in a prior notice would be a very complex and time-consuming, if not an impossible, task. FDA suggests that its Prior Notice System was developed to accommodate submission of up to three different growers. Clearly this feature of FDA’s Prior Notice System was not developed to accommodate the produce industry. United requests that FDA consider two alternatives which would alleviate the problems associated with compliance in reporting excessive grower information:

- First, in lieu of requiring listing of all known growers in the prior notice, the rule should require the submitter of the prior notice to retain a complete list of growers and to make this list available to FDA for inspection and copying upon request.
- Second, an exception could be granted from the reporting of known grower information for small farms. By instituting a small-farm exception based on acreage amount, the number of growers required to be reported in the prior notice would decrease substantially.

We believe that these options would reduce the redundant burdens that this requirement would impose on importers, while having a negligible impact on the ability of FDA to screen for safety risks of imported foods.

## **Flexibility in Setting Prior Notice Requirements**

We commend FDA for adding a reasonable amount of flexibility for the submission of prior notice based on the mode of transport. The import community wishes to aid FDA in its mission of keeping the U.S. food supply safe, pure, and abundant. As importers of fresh and highly perishable fruits and vegetables, we have long believed that a one-size-fits-all approach in establishing a time period for prior notice is not workable for all shipments crossing our borders. We believe that the current prior notice rule now reflects the current commercial realities and practices of the importing business for these commodities.

## **Definition of “Food”**

We commend FDA for its consideration of our comments to exclude “substances that migrate into food from food packaging and other articles that contact food” from the definition of “food.” Clearly the intent of the prior notice provision of the Bioterrorism Act is for FDA to

receive advance notice of imports of food products, not immediate food packaging or agricultural chemicals.

United has reservations, however, regarding the agency's definition of food "no longer in its natural state." Prior notice is required for food "no longer in its natural state," meaning a product made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Activities relevant to fresh fruits and vegetables that render food no longer in its natural state include cutting, peeling, trimming, washing, waxing, labeling, or packaging. But, crops that have been cleaned (*e.g.*, dusted, washed), trimmed, or cooled as part of harvest or collection *are still in their natural state* for purposes of the prior notice interim final rule.

The produce industry considers activities such as trimming, washing, waxing, and packaging to be part of normal harvesting activities. Therefore, we believe that produce that has been trimmed, washed, waxed, and/or packaged should be defined as food that is still in its natural state. In our view, such produce has not been "manufactured/processed" and, therefore, the farm that produces it should not be required to register. (*See United's comments on the Interim Final Rule for Registration of Food Facilities*).

## **Conclusion**

In conclusion, United's members strongly support the goals of the Bioterrorism Act to strengthen the safety of our food supply and the efforts by the FDA to implement the statute. Perishable fruits and vegetables lose quality and, therefore, market value very quickly. Delays of as little as 24 hours can substantially affect value and marketability. If the prior notice requirement that FDA imposes is not practicable, there will be disruptions in the supply of food to consumers and serious trade ramifications with our trading partners. The produce industry is committed to ensuring the security of its products. The industry is proud of the contribution it makes to the health of Americans by providing wholesome foods essential for good health. It is important to always consider that increasing the consumption of fresh fruits and vegetables is a critical component of U.S. public health policy, and that improved security resulting from bioterrorism risk management steps are properly weighed against the public health impact of increased cost and reduced availability of fresh produce. It is important for the Secretary to keep in mind that the produce industry produces and markets highly perishable items and that time is a very valuable commodity. Timely decision-making is critical to the viability of our industry. Thank you for the opportunity to comment. We look forward to continuing to work together with the FDA on these important matters.

Sincerely,

Donna M. Garren, Ph.D.  
Vice President, Scientific and Technical Affairs  
United Fresh Fruit and Vegetable Association